SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

a. Submitter: Vascular Control Systems, Inc.
32236-E Paseo Adelanto
San Juan Capistrano, CA 92675
(949) 488-8700

b. Contact Person: Al Memmolo
Vice President, Regulatory Affairs/Quality Assurance
(949) 488-8700 ext. 108

c. Date Summary Prepared: September 20, 2002

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: VCS-A Series Vascular Clamp with Doppler Ultrasound

b. Classification names: Vascular Clamp / Diagnostic Ultrasound Transducer
(21 CFR §870.4450, 21 CFR §892.1570)

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

A. ***510(k) #:*** **K011863**
Company: **Vascular Control Systems, Inc.**
Device Classification: **Class II**
Device Name: **VCS-A Series Clamp with Doppler Ultrasound**
Clearance *Date:* **February 15, 2002**

B. ***510(k) #:*** **K973080**
Company: **Walter Lorenz Surgical, Inc.**
Device Classification: **Class II**
Device Name: **Surgical Vascular Clamp**
Clearance *Date:* **February 23, 1998**

C. ***510(k) #:*** **K935994**
Company: **Koven Technologies, Inc.**
Device Classification: **Class II**
Device Name: **PW Doppler Vascular Probes**
Clearance *Date:* **May 11, 1995**

4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The VCS-A Series Clamp is a ring-handled instrument with integrated Doppler sensor, which allows temporary occlusion of blood vessels. The Doppler sensor allows audible sensing of blood flow by connecting to a commercially available portable transceiver box. The VCS-A series Clamp is manufactured from stainless steel.

5. **Statement of intended use:**

The VCS-A Series Clamp is intended for use in the temporary occlusion of blood vessels during vascular surgical procedures.

6. **Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.**

The modified VCS-A Series Clamp and the predicate device are both intended for temporary occlusion of blood vessels using an 8 MHz pulsed-wave Doppler sensor. The modifications to the VCS-A Series Clamp do not affect the intended use or scientific technology of the device.

7. **Brief summary of nonclinical tests and results:**

The VCS-A Series Clamp has been designed and tested to comply with the requirements of IEC 60601-1 for electrical and thermal safety. Acoustic output power measurements were performed in accordance with the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. Test results indicate reliable performance when the device is used in accordance with the Instructions for Use. The modified VCS-A Series Clamp does not raise new issues of safety, effectiveness, or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 2002

Vascular Control Systems, Inc.
c/o Mr. Al Memmolo
Vice President of Quality Assurance
and Regulatory Affairs
32236-E Paseo Adelanto
San Juan Capistrano, CA 92675

Re: K023154
VCS-A Series Clamp
Regulation Number: 21 CFR 870.4450 and 892.1570
Regulation Name: Vascular clamp and Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: 72 DXC and 90 ITX
Dated: September 20, 2002
Received: September 23, 2002

Dear Mr. Memmolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Vascular Technology (VTI) Doppler Transceiver, 8 MHz Selectable Channel REF 108900-40, as described in your premarket notification:

Transducer Model Number
09-0007-01
09-0007-02
09-0008-01
09-0008-02

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In this notification, you have provided 510(k) special reports, dated September 20, 2002 and October 18, 2002, for the four subject devices specified above.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact O.D. Hottenstein, Ph.D., at (301) 443-8262, extension 163.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known): K023154

Device Name: VCS-A-Series Clamp with Doppler Ultrasound

Indications for Use:

The VCS-A Series Clamp is intended for use in the temporary occlusion of blood vessels during vascular surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K023154

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of he human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)**Vascular**				P						
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: VCS-A Series Clamp with Doppler Ultrasound, Model 09-0008-01
The transducer is specified for use with the Vascular Technology, Inc. Doppler Transceiver,
8 MHz Selectable Channel, VTI P/N 108900-40.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of he human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)**Vascular**				P						
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: VCS-A Series Clamp with Doppler Ultrasound, Model 09-0008-02
The transducer is specified for use with the Vascular Technology, Inc. Doppler Transceiver,
8 MHz Selectable Channel, VTI P/N 108900-40.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)